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In re Application of
Matthew HALL

Atty. Dkt. No.: 2857-001

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Title: FLEXIBLE FULL FACE MASK FOR CPAP TREATEMENT

SUBSTITUTE SPECIFICATION UNDER TO 37 CFR 1.125(b)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant requests entry of the substitute specification. The substitute specification contains no new matter. A marked up version of the substitute specification showing all the changes (including the matter being added to and the matter being deleted from) to the specification of record is provided herewith. A clean copy of the substitute specification is also provided herewith.

The Commissioner is hereby authorized to debit Deposit Account No. 18-1579 in the amount of $660.00. The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 18-1579. The Commissioner is also authorized to charge Deposit Account No. 18-1579 for any future fees connected in any way to this application.

Respectfully Submitted,

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505-922-1400

Date: August 12, 2004

Atty. Docket No.: 2857-001

SUBSTITUE SPECIFICATION

TITLE: FLEXIBLE FULL-FACE MASK FOR CPAP TREATMENT

INVENTOR: MATTHEW HALL

RELATED APPLICATIONS

[01] This application claims priority to U.S. Provisional Application Ser. No. 60/439,073, filed January 9, 2003.

BACKGROUND OF THE INVENTION

[02] CPAP (Continuous Positive Airway Pressure) is used to treat Obstructive Sleep Apnea (OSA) by delivering a fixed pressure of normal room air. This air pressure supports the airway by acting like an artificial splint, thereby preventing the airway from collapsing during sleep. CPAP is considered the most successful, non-invasive way of treating OSA and other sleep related breathing disorders.

[03] The most common type of mask used for CPAP treatment is a nasal mask that covers only the nose of the patient. This type of mask is popular because of its small size and its ability to fit a large variety of faces. However, it is not effective if the user breathes through their mouth, so numerous gadgets have been employed to assure the user's mouth is closed, such as chinstraps and lip clamps. A more optimum solution is a full-face mask that covers both the nose and mouth.

[04] CPAP full-face masks are less common than nasal masks and typically consist of a clear, rigid shell dimensioned to cover the nose and mouth and a flexible, cushioned seal for contacting the users face. To properly fit the user, seals are usually provided in a variety of sizes and can often involve the expense of purchasing and trying-out of

multiple seals prior to finding a sufficiently comfortable and effective seal. Other problems encountered with prior art CPAP full-face masks, like the Mirage® Full-face Mask Series 1 & 2 from ResMed® and the Spectrum® Reusable Full-face Mask from Respironics® include breakage of the rigid shell, difficult servicing and cleaning due to the large number of small parts (most of which are clear and can easily be lost), high cost, difficult manipulation of head straps for consistent fit, difficult manipulation of port covers by the elderly, sores caused when users roll and put pressure on the rigid shell (that, in turn, presses against the face), unintended disassembly of the elbow when users manipulate the mask by grasping the release prongs of the elbow, and poor location of exhalation ports that tend to bother a user's bedmate due to outwardly directed air flow (preventing "spooning"), further altering a user's lifestyle.

[05] Indeed, the high cost and complication of prior art CPAP full-face masks make them undesirable, unaffordable and/or unusable to many people who could benefit from CPAP treatment.

[06] The present invention is drawn to a CPAP full-face mask that employs a flexible shell to allow a single device to comfortably fit a wide variety of users. It preferably employs a positionable guide wire at a periphery of the shell to allow the periphery of the flexible shell to be deformed to conform to the shape of a users face. It additionally uses a simpler design to allow lower cost and improved ease of use, as further discussed below.

BRIEF SUMMARY OF THE INVENTION

[07] The present invention provides a CPAP full-face mask with a flexible shell and positionable guide wire to allow a single size of mask to comfortably fit a wide variety of

users.

[08] It is an object of the invention to provide a CPAP full-face mask that eliminates the hard plastic frame that can dig into a user's face.

[09] It is another object of the invention to provide a CPAP full-face mask that eliminates the need for multiple seal sizes.

[10] It is a further object of the invention to provide a CPAP full-face mask that includes an integrated, two-layer seal to eliminate the complication of seal installation and replacement.

[11] It is an object of the invention to provide a CPAP full-face mask that is inexpensive enough and durable enough to be replaced annually.

[12] It is yet another object of the invention to provide a CPAP full-face mask having a reduced number of parts.

[13] It is an object of the invention to provide a CPAP full-face mask having components formed of latex-free material.

[14] It is a further object of the invention to provide a CPAP full-face mask having components formed of opaque or colored material to assist in locating misplaced components.

[15] It is an object of the invention to provide a CPAP full-face mask having easily manipulated components for the elderly and disabled.

[16] It is another object of the invention to provide a CPAP full-face mask having a less-

complicated, more reliable elbow design.

[17] It is yet a further object of the invention to provide a CPAP full-face mask having a less obtrusive exhalation port.

[18] It is an object of the invention to provide a CPAP full-face mask having a comfortable seal.

[19] It is another object of the invention to provide a CPAP full-face mask having an easy to use and stable five-point harness.

BRIEF DESCRIPTION OF THE DRAWINGS

[20] **Figure 1** illustrates a perspective view of one embodiment of the present invention.

[21] **Figure 2** illustrates a side view of one embodiment of the present invention.

[22] **Figure 3** illustrates a front view of the CPAP mask according to one embodiment of the present invention;

[23] **Figure 4** illustrates a back view of the flexible CPAP full-face mask according to one embodiment of the present invention;

[24] **Figure 5** illustrates an exploded view of the elbow attachment assembly according to one embodiment of the present invention;

DETAILED DESCRIPTION OF THE INVENTION

[25] Referring now to **figure 1**, a perspective view of one embodiment of the present invention is illustrated. In a preferred embodiment of the present invention, the flexible

shell of the CPAP full-face mask is fabricated from flexible, latex-free material such as polyurethane formed in a conventional manner. The result is a flexible shell that is soft and smooth to the touch, unlike the hard shells of the prior art. The flexibility of the shell allows both greater comfort due to a better, customized fit and increased durability due to its ability to bend to resist breakage while forming a air pressure seal. The custom fit and durability ensure long-term leak-free use. A strap buckle **101** allows a user to easily attach head gear (not shown) or retaining straps for attaching to a mask of the present invention. Head gear or retaining straps are attached to the strap buckle **101** via attachments **103**. Additional head gear attachment points attach at the forehead strap attachment points **107**. A cushion **105** is attached to the mask and lays against the users face. A contour wire (not shown) which is also referred to herein as guide wire, is positioned at the inner edge of the mask and helps shape the mask to contour to multiple facial sizes and shapes, and accommodate facial hair. A swivel assembly **109** removable attaches to the mask.

[26] Referring now to **figure 2**, a side view of the mask is illustrated.

[27] Referring now to **figure 3**, a continuous positive air pressure (CPAP) mask is illustrated according to one embodiment of the present invention. To provide a secure fit on the user, the CPAP full-face mask of the present invention preferably uses a five-point harness comprising three forehead attachments **303**, and two lower, side attachments **309.** According to one embodiment of the present invention, the CPAP mask is molded of polyurethane. The polyurethane construction allows a bit of stretch to these attachment points, thereby adding comfort and flexibility to the user of the mask. To ease installation and removal, the lower attachments **309**, preferably employ an inexpensive

and standard (i.e., easily replaced) quick-release clip that has large detents, to again ease manipulation by those with arthritic hands or disabilities. By eliminating the use of hook-and-loop harnesses, the present invention insures a correct fit.

[28] Port covers **313** cover openings for tubes that carry oxygen or other gas to the user. The port covers **313** are shaped to have corners (i.e., square) to ease manipulation by those with arthritic hands or disabilities such as syndactyly, who can often have problems with the prior art circular-shaped port covers. The flexible shell of the CPAP mask and its associated components (other than the integrated seal) are formed of opaque and/or colored material to make the parts easier to locate.

[29] A port **315** for attaching a rigid elbow (not shown) that delivers the positive airway pressure to the user is illustrated. The attachment of the elbow to a port **315** in the flexible CPAP mask provides that the flexible CPAP mask will absorb forward or lateral force applied to the elbow without causing displacement of the flexible CPAP mask to the same degree that occurs when the same degree of forward or lateral force is applied to an elbow attached to a rigid CPAP mask.

[30] Referring now to **figure 4**, a back view of the CPAP mask **401** according to one embodiment of the present invention is illustrated. The seal used by the present invention according to this embodiment, is preferably a two layer seal, having an inner or first, silicone gel-filled portion **405**, and an outer or second, flexible silicone portion with an open, U-shaped cross-section that "balloons" and is gently urged by the positive air pressure to form a seal against user's face, as is known in the art. The silicone gel portion of the seal provides better user comfort and user protection than foam or air-filled

cushions.

[31] In a preferred embodiment, this seal is integrated or permanently fixed, such as by adhesive, to the flexible shell portion to eliminate the need for specific seal attachment structure on the shell. This also eliminates the requirement for the user or technician to install/replace the seal mechanism, as well as the requirement for pharmacies to stock replacement seals and their associated components. Additionally, the integrated seal cannot accidentally become detached during routine use/cleaning and does not need to be disassembled to clean interior portions. An integrated seal is allowed by the adjustable nature of the flexible shell (and guide wire) of the present invention that allow a single size shell/seal combination to be used with a wide variety of face sizes and shapes.

[32] The flexible shell of the CPAP full-face mask of the present invention preferably includes a positionable contour wire also referred to as a guide wire (not shown) in the peripheral portion adjacent the seal to allow the periphery of the flexible shell to be positioned so as to conform to the face of individual users. Although this "guide wire" will typically be a metal wire of suitable stiffness that is molded into the periphery of the shell, the term is not meant to be so limiting. As used herein, "positionable guide wire" refers to any structure that can be positioned adjacent or within the periphery of the flexible mask and which can be deformed/positioned to generally conform the periphery of the mask shell to the contours of a user's face. Alternatives to embedded metal wire can include embedded metal strips, surface-mounted metal wires, surface mounted metal strips (i.e., similar to a gasket), embedded or surface mounted structures made up of a plurality of positionable metal or plastic links, and moldable clay or plastic rings.

[33] The flexible nature of the shell used in the CPAP full-face mask of the present invention provides additional comfort to users and those sleeping with users since there is no hard shell to impact or push against a user or bedmate. Although a rigid elbow is still part of the present invention, it is now mounted to a flexible shell so as to be resilient when pushed against objects or persons. Side headgear attachment site **409** are threaded to the attachment of the buckle. Three forehead attachment sites **411** accept head gear to provide for five points of attachement or less depending on the level of secure fit desired by the wearer.

[34] Another aspect of the present invention is illustrated in **figure 5** wherein an improved elbow is provided. CPAP users often manipulate their mask by grasping the elbow protruding from the front of the mask to use as a handle. A common prior art design, uses a pair of prongs for elbow attachment. These prongs are subject to damage and inadvertent activation when grasped by users to manipulate a mask. Referring now to **figure 5**, prongs are eliminated on the elbow of the present invention. A more reliable elbow assembly is illustrated in wherein a threaded male **507** couples to a female acceptor **513** forming a locking assembly. A membrane **511** is placed within the locking assembly. Alternately, the present invention could also employ a flexible or resilient press-fit (not illustrated) to attach the elbow in order to further reduce the number of parts. Such a press-fit is possible due to the flexible nature of the mask material.. Additionally, the present invention provides an exhalation vent **509** and clip-on vent cover **503** on the elbow portion **501**of the assembly **500**. Numerous advantages are gained by placing the exhalation vent **509** in this manner. The mask frame (not shown) is cheaper and easier to produce without an exhalation vent. Elbows and exhalation vents

typically have a different service life than masks and thus can be replaced independently from the mask of the present invention. Placement of the exhalation vent **509** on the elbow also allows more options regarding the direction of the exhaled air. It can be directed parallel to the mask so as no to directly impinge on bedmates and further diffused or directed away from bedmates by use of a clip-on cover. Although the cover is disclosed with respect to a preferred embodiment, numerous other arrangements are within the skill of one in the art to provide covers, clip-on or otherwise, to diffuse and/or direct exhaled air in a non-objectionable manner. A tab to release and lock the elbow to a frame **515** and a locking clip **517** are also illustrated. Finally, as illustrated in **figure 5**, a swivel **505** provides for a swivel movement of the elbow once attached to a fixed air supply. Flexible tabs engage the interior of the mating swivel element of the air supply tube thereby eliminating the swivel attachment clip of the prior art that can easily be lost or accidentally disengaged. Components illustrated in **figure 5** are typically formed from a polycarbonate

[35] As discussed herein, the CPAP full-face mask of the present invention provide many advantages over prior art due to its flexible nature, which allows a single configuration to be used with a wider range of user face sizes and shapes, thereby reducing complexity and costs. The flexible nature of the shell, ergonomic design of components and integrated two layer seal allows greater user comfort, increased ease of use and simplified periodic maintenance/replacement of the mask.

[36] Additionally, for individuals with different shaped faces the present invention can accommodate changes in the face during the life span of the mask without the need to purchase a new mask or seal, as would be necessary when using prior art devices. This is

particularly beneficial to individuals undergoing facial surgery to correct deformities, people experiencing changes in weight or for individuals experiencing acute changes in facial structure. One problem for patients with certain conditions that require silicon implants in the cheeks (e.g., to stretch the skin) is that the cheeks are positioned high, therefore prior art masks cannot conform to the face in the same manner as the present invention. It could also be of benefit to those individuals who fluctuate in weight or have facial hair periodically.

[37] Although described herein with respect to a preferred embodiment, the present invention is not meant to be so limited, and other modifications and embodiments that fall within the scope of the present invention will readily apparent to those of skill in the art and is limited only by the claims, attached below.